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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Norbert Schulke et al.

Serial No.: 10/804,802 Examiner: Sanjoo Shree Jalla

Filed : March 19, 2004 Art Unit: 1644

For : CD4-IgG2 FORMULATIONS

1185 Avenue of the Americas
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July 24, 2006

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Commissioner for Patents
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Sir:

COMMUNICATION IN RESPONSE TO JANUARY 25, 2006 OFFICE ACTION AND PETITION FOR FIVE-MONTH EXTENSION OF TIME

This Communication is submitted in response to the January 25, 2006 Office Action issued by the United States Patent and Trademark Office in connection with the above-identified application. A response to the January 25, 2006 Office Action was due February 25, 2006. Applicants hereby petition for a five-month extension of time. The fee for a five-month extension of time for a small entity is ONE THOUSAND EIGHTY DOLLARS ($1,080.00) and a check for this amount is enclosed. With a five-month extension of time, a response to the January 25, 2006 Office Action is now due July 25, 2006. Accordingly, this Communication is being timely filed.

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Restriction Requirement:

In the January 25, 2006 Office Action, the Examiner required restriction under 35 U.S.C. §121 of pending claims 1-141 to one of the three allegedly patentably distinct inventions.

I. Claims 1-110 and 133-141, drawn to a pharmaceutical formulation comprising a CD4-IgG2 chimeric heterotetramer and a histidine buffer, an article of manufacturing, and a kit;

II. Claims 111-113, drawn to a method of inhibiting infection of a CD4+ cell by a human immunodeficiency virus, comprising contacting the HIV with the formulation or administering it to the subject; and

III. Claims 114-132, drawn to a method of making a pharmaceutical formulation comprising a CD4-IgG2 chimeric heterotetramer from a source in the presence of a histidine buffer.

The Examiner also stated that if Group I is elected, applicants are required to elect a specific formulation, wherein the formulation is selected from the group consisting of CD4-IgG2 chimeric heterotetramer, a histidine buffer and:

a) an amino acid stabilizing agent,
b) a lyoprotectant,
c) a non-ionic detergent, or
d) an osmolality adjusting.

The Examiner stated that claims 1-28 and 133-137 are generic claims, and required that applicants list all claims reading on the elected species.

On page 3 of the January 25, 2006 Office Action, the Examiner also stated that the restriction is between product and process claims. Applicants maintain that where claims directed to a product are elected,

and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all limitations of the allowable product claim will be rejoined in accordance with M.P.E.P. §821.04. Applicants understand that in the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. §1.104.

In response to the restriction requirement, applicants hereby elect, with traverse, to prosecute the invention identified by the Examiner as Group I, claims 1-110 and 133-141. In addition, in response to the species election requirement, applicants hereby elect species (a) an amino acid stabilizing agent. The claims in Group I which read on species (a) are claims 1-41, 100-110, and 133-141. Applicants request that claims that read on the non-elected species be reconsidered, if any of generic claims 1-28 and 133-137 are found allowable.

Applicants, however, respectfully request that the Examiner reconsider and withdraw the restriction requirement. Under 35 U.S.C. §121, restriction may be required if two or more independent and distinct inventions are claimed in one application. Nevertheless, under M.P.E.P. §803, the Examiner must examine the application on the merits if examination can be made without serious burden, even if the application would include claims to distinct or independent inventions. That is, there are two criteria for a proper requirement for restriction: (1) the invention must be independent and distinct, and (2) there must be a serious burden on the Examiner if restriction is not required.

Applicants respectfully submit that there would not be a serious burden on the Examiner if restriction were not required, because a search of the prior art relevant to the claims of Groups II and III would not impose a serious burden once the prior art relevant to Group I has been identified. Therefore, there would be no serious burden on the Examiner to examine Groups I-III together in the subject application.

In addition, applicants submit that there would not be a serious burden on the Examiner if a species election were not required, because a